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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,044	04/18/2001	Matthew R. Kaser	PB-0011-1 DIV	2961

7590 04/23/2002

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PATENT DEPARTMENT
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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,044	KASER ET AL.	
	Examiner	Art Unit	
	Quang Nguyen	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a substantially purified nucleic acid molecule expressed in response to polycyclic aromatic hydrocarbon exposure, classified in class 536, subclass 23.1.

II. Claims 3-6, drawn to a method of using a nucleic acid molecule to screen a library of molecules or compounds to identify at least one ligand which specifically binds the nucleic acid molecule, classified in class 436, subclass 501.

III. Claims 7-8, drawn to a ligand that modulates the activity of a nucleic acid molecule of the presently claimed invention, can not be classified because no compound is recited.

IV. Claims 9-10, drawn to a method of using a nucleic acid molecule to purify a ligand which specifically binds the nucleic acid molecule, classified in class 435, subclass 6.

V. Claims 11-12, drawn to a method for diagnosing a disorder or condition associated with the altered expression of a gene expressed in response to polycyclic aromatic hydrocompound exposure in a plurality of biological samples, classified in class 435, subclass 6.

VI. Claims 13-14, drawn to a method for detecting or diagnosing effect of a compound on expression level of at least one nucleic acid molecule in a subject, classified in class 435, subclass 6.

VII. Claims 15-19, drawn to a substantially purified protein expressed in response to polycyclic aromatic hydrocarbon exposure, classified in class 530, subclasses 300 or 350, class 514, subclass 2.

VIII. Claims 20-21, drawn to a method for using a protein to screen a library of molecules or compounds to identify at least one ligand which specifically binds the protein, classified in class 435, subclass 7.1.

IX. Claim 22, drawn to a ligand that modulates the activity of the protein, can not be classified because no compound is recited.

X. Claim 23, drawn to a method of using the protein to purify a ligand from a sample, classified in class 435, subclass 7.1.

XI. Claims 24, 26-27, 29 and 36-37, drawn to an antibody which specifically binds to the protein of the presently claimed invention, classified in class 424, subclasses 130.1, 133.1, 135.1, 141.1, for examples.

XII. Claim 25, drawn to a diagnostic test for a condition or disease associated with the expression of a protein in a biological sample using an antibody, classified in class 435, subclass 7.1.

XIII. Claims 28 and 30, drawn to a method of diagnosing a condition or disease associated with the expression of a protein in a subject using an antibody, classified in class 424, subclass 130.1.

XIV. Claim 31-33, drawn to a method of preparing a polyclonal antibody, a polyclonal antibody prepared by the same method and a composition comprising the same polyclonal antibody, classified in class 424, subclass 130.1.

XV. Claims 34-35, drawn to a method of making a monoclonal antibody, a monoclonal antibody prepared by the same method and a composition comprising the same monoclonal antibody, classified in class 424, subclass 141.1.

XVI. Claim 38, drawn to a method for detecting a protein in a sample using an antibody, classified in class 435, subclass 7.1.

XVII. Claim 39, drawn to a method of purifying a protein from a sample using an antibody, classified in class 530, subclass 413.

The inventions are distinct, each from the other because of the following reasons:

Group I and groups II, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a substantially purified nucleic acid molecule of invention I can be used in any of the materially different processes of inventions II, IV, V and VI.

Group VII and groups VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a substantially purified protein of invention VII can be used in any of the materially different processes of inventions VIII and X.

Group XI and groups XII, XIII, XVI and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, an antibody of invention XI can be used in any of the materially different processes of inventions XII, XIII, XVI and XVII.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between Groups II, IV, V, VI, VIII, X, XII, XIII, XIV, XV, XVI and XVII because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different starting materials.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper between groups I, III, VII, IX and XI, because these products appear to constitute patentably distinct inventions representing different

biochemical compounds comprising different structures, functions and biochemical activities. For examples, a purified nucleic acid molecule of group I, a purified protein of group VII, an antibody of group XI and ligands of groups III and IX are chemically and biochemically distinct.

Should Applicants elect the invention of group II or III, **further group restriction** is required because claims 3, 4, 5, 6 and 7-8 comprise a plurality of disclosed patentably methods using patentably distinct libraries of molecules or compounds and patentably distinct ligands (molecules or compounds): (a) DNA or RNA molecules, (b) peptide nucleic acids, (c) mimetics, and (d) proteins that lack unity of invention. Applicants are required under 35 U.S.C. 121 to elect a specific method utilizing a patentably distinct library of molecule or compound for the invention of group II or a specific patentably distinct ligand for the invention of group III.

Should Applicants elect the invention of group VIII or IX, **further group restriction** is required because claims 20, 21 and 22 comprise a plurality of disclosed patentably methods using patentably distinct libraries of molecules or compounds, and patentably distinct ligands, respectively: (a) DNA or RNA molecules, (b) peptide nucleic acids, (c) mimetics, (d) proteins, (e) agonists, (f) antagonists, and (g) antibodies that lack unity of invention. Applicants are required under 35 U.S.C. 121 to elect a specific screening method using a patentably library of molecules or compounds for the invention of group VIII or a specific patentably distinct ligand for the invention of group IX.

Additional group restriction is required because there is a lack of unity of invention among DNA or RNA molecules, peptide nucleic acids, mimetics, proteins, agonists, antagonists and antibodies that do not share any substantial common structural or functional properties. Accordingly, these claims are subject to restriction under 35 U.S.C. 121. This requirement is not to be construed as a requirement for an election of species, since each of the above recited in alternative form are not members of a single genus of invention, but independent and distinct inventions.

Because these inventions are distinct for the reasons set forth above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups, and each and vice versa, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect the invention of group XI, XII, XIII, XVI or XVII, claims 24-30, 37 and 38-39 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named antibody listed in the Markush group of claim 26.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER